MAR - 3 2000

K000200

510(k) Summary (Section 807.93)

Application: Ureteroscope

A. Indication for use

Our Ureteroscopes are used to examine the urether and, using additional accessories, to perform various diagnostic and therapeutic procedures.

B. Summary of Safety and Effectiveness

We compared our Uretheroscope prototypes in detail to much older equipment manufactured by Wolf and other Manufacturers. We conclude that our Ureteroscopes are as safe and effective as all other devices earlier and currently on the market. Our designs, lens-systems, materials, glues and epoxies are commonly used by the endoscope industry.

C. Parts of finding Substantial Equivalence

We compared our manufacturing drawings with corresponding devices from Wolf We found substantial equivalence in all significant details.

D. Descriptive Information

We intend to manufacture our Ureteroscope under strict GMP Guidelines: From incoming material registration and testing to detailed manufacturing instructions and device master and history filing including complaint reporting.

E. Performance Testing

Our Prototypes underwent extensive mechanical and thermic stress testing to asure safe and long term use.

F. Adverse Health Effects

We are not able to determine any adverse health effects compared to the already marketed devices and cannot imagine any possibility of this kind.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2000

Mr. Cornel M. Topala
President
CorTek Endoscopy, Inc.
501 W. Colfax
Suite B
Palantine, IL 60067

Re: K000200
CorTek Ureteroscope and Accessories
Dated: January 20, 2000
Received: January 21, 2000
Regulatory Class: II
21 CFR 876.1500/Procode: 78 FGB

Dear Mr. Topala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Device Name: CorTek Endoscopy, Inc. Ureteroscope

Indications for Use:

Our Ureteroscopes are used to examine the urether and, using additional accessories, to perform various diagnostic and therapeutic procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.1091

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000200